No. 17-1484

In The Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF FOR RESPONDENTS ALLINA HEALTH SERVICES ET AL.

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QUESTION PRESENTED

This case concerns the decision by the Department of Health and Human Services to forgo notice-and-comment rulemaking in a unique circumstance: when readopting a change in a substantive legal standard governing Medicare payment to hospitals nationwide after a notice-and-comment rule attempting to adopt the same change was vacated for a logical-outgrowth failure. That change, which the Government incorrectly dismisses as "contractor instructions," would deprive hospitals of billions of dollars in Medicare payments for past services to low-income patients.

The question presented is:

Whether 42 U.S.C. § 1395hh(a)(2) or § 1395hh(a)(4) required the Department of Health and Human Services to conduct notice-and-comment rulemaking before providing the challenged instructions to a Medicare Administrative Contractor making initial determinations of payments due under Medicare.

PARTIES TO THE PROCEEDING

Respondents are the private non-profit organizations identified below, who were plaintiffs in the district court and appellants in the court of appeals:

1. Allina Health System d/b/a Abbott Northwestern Hospital

2. Allina Health System d/b/a United Hospital

3. Allina Health System d/b/a Unity Hospital

4. Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital

5. Montefiore Medical Center

6. Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center

7. New York - Presbyterian / Queens

8. New York Presbyterian Brooklyn Methodist Hospital

9. The New York and Presbyterian Hospital

Petitioner Alex M. Azar, II, Secretary of Health and Human Services, was defendant in the district court and appellee in the court of appeals.

RULE 29.6 DISCLOSURE

There are no parent companies, and no publicly held corporation owns 10 percent or more of any respondent's stock.

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RELEVANT STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced in an addendum to this brief. Add. 1a-30a.

INTRODUCTION

In 2004, via notice-and-comment rulemaking, the Secretary of Health and Human Services ("HHS") attempted to change the standard governing Medicare payment for services furnished to low-income patients by hospitals nationwide. The agency botched that rulemaking: the final rule (ignoring its fiscal impact) was not the "logical outgrowth" of the proposed rule, and the D.C. Circuit vacated it. Days later, the agency attempted to make the same change, this time *without* undertaking any notice and comment. That renewed

attempt—the focus of this case—fails as well because two subsections of the Medicare Act, Sections 1395hh(a)(2) and 1395hh(a)(4), independently require the agency to engage in notice-and-comment rulemaking before the change can take effect.

The Government's effort to revive the faulty 2004 about-face without notice and comment relies on arguments that find no support in the text, structure, or purpose of the Medicare Act's special notice-and-comment requirements. Instead of applying the plain terms of Sections 1395hh(a)(2) and 1395hh(a)(4), the Government seeks shelter under "principles" of the Administrative Procedure Act ("APA"). But by conflating the two statutes, the Government ignores critical distinctions between them. Those distinctions include the Medicare Act's express recognition that a policy statement (which is not binding or subject to notice and comment under the APA framework), requirement (not mentioned in the APA), or rule (of any type) is capable of triggering the notice-and-comment mandate if it has the requisite substantive effect. The differences also include the Medicare Act's selective incorporation of the APA's explicit good-cause exemption but not its explicit interpretive-rule exemption. The Government's contorted attempt to conjure up an interpretive-rule-like exemption reads key terms out of the Medicare Act, and stands on unfounded speculation about the legal landscape and legislative history.

As the D.C. Circuit concluded, the agency cannot evade the specific notice-and-comment requirements Congress enshrined in the Medicare Act when altering

a substantive legal standard that reduces payments to hospitals—to the tune of billions of dollars. This Court should affirm.

STATEMENT OF THE CASE

I. MEDICARE PROGRAM

A. Special Notice-And-Comment Rulemaking Requirements

The federal Medicare program furnishes health-insurance benefits to elderly and disabled individuals. When it first enacted the Medicare program in 1965, Congress gave the agency general authority to prescribe regulations for administering the program. Social Security Amendments of 1965, Pub. L. No. 89-97, Title I, § 102(a), 79 Stat. 286, 331 (codified at 42 U.S.C. § 1395hh(a)(1)). Congress did not specify at that time whether those regulations required notice-and-comment rulemaking, or when Medicare policies required promulgation by regulation.

In 1971, the agency announced a policy of following the APA's notice-and-comment procedures for rules relating to Medicare benefits. Although the APA exempts rules related to "benefits" from its notice-and-comment requirements, 5 U.S.C. § 553(a)(2), the agency stated that it would engage in notice-and-comment rulemaking even "where not required by law." 36 Fed. Reg. 2,531, 2,532 (Feb. 5, 1971) (stating the agency would "utilize the public participation procedures of the APA" in issuing "rules and regulations relating to *** benefits").

In the early 1980s, Congress "fundamentally overhauled the Medicare reimbursement methodology," beginning with inpatient hospital care. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999). Instead of reimbursing hospitals for the "reasonable costs" of inpatient care, Medicare began "reimburs[ing] qualifying hospitals at prospectively fixed rates" set annually each year by categories of patient diagnoses. *Id.* Thereafter, Congress made several amendments to the procedures required for promulgating Medicare policies, including for that prospective payment rate setting.

In 1986, Congress mandated for the first time that the agency follow notice-and-comment procedures, and articulated some requirements different from those under the APA. Specifically, Congress required a 60-day notice-and-comment period for Medicare regulations subject to three limited exceptions. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e)(1), 100 Stat. 1874, 2017 (codified at 42 U.S.C. §§ 1395hh(a)(1), 1395hh(b)). The exceptions are: (1) where a statute specifically permits no prior public comment or a shorter comment period; (2) where a statute specifies a rulemaking deadline that falls within 150 days of its enactment; or (3) where the APA's "good cause" exemption (5 U.S.C § 553(b)(B)) is satisfied. 42 U.S.C. § 1395hh(b).

A year later, still concerned that "important policies [were] being developed without benefit of the public notice and comment period," H.R. REP. NO. 100-391(I), at 430 (1987), Congress further amended the Medicare statute to specify the kinds of policy changes

that require adoption by regulation after notice and comment. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035, 101 Stat. 1330, 1330-78. Pursuant to those amendments, the statute now mandates:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation [through notice-and-comment rulemaking].

42 U.S.C. § 1395hh(a)(2); *see also id.* § 1395hh(a)(1) (defining agency's authority to prescribe regulations); *id.* § 1395hh(b)(1) (requiring notice and comment before issuing any regulation under subsection (a)).

When it adopted that language in 1987, Congress went a step further to ensure advance notice of Medicare policy changes. When "manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" are *not* required to be promulgated by notice and comment, Congress nonetheless required them to be published on a list in the Federal Register. Omnibus Budget Reconciliation Act of 1987, § 4035 (codified at 42 U.S.C. § 1395hh(c)(1)).

In 2003, Congress further modified the Medicare Act, again insisting on notice-and-comment rulemaking in circumstances where the APA does not require it:

> If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 902, 117 Stat. 2066, 2375 (codified at 42 U.S.C. § 1395hh(a)(4)).

At the same time, Congress addressed the retroactive application of substantive Medicare policy. It mandated that a "substantive change" made in any of several forms of administrative issuances—whether in "regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability"—"shall not be applied *** retroactively to items and services furnished before the effective date of the change," except under circumstances not applicable here. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 903 (codified at 42 U.S.C. § 1395hh(e)(1)(A)). It also provides that "no action shall be taken against a provider of services or supplier with respect to non-

compliance with such a substantive change." 42 U.S.C. § 1395hh(e)(1)(C).

B. Part A Fee-For-Service And Part C Managed Care Programs

Under Medicare Part A, the Government makes direct payments to hospitals for inpatient hospital services on a fee-for-service basis. 42 U.S.C. § 1395ww(d); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011). The standard per-patient-discharge rates at which hospitals are paid are predetermined, but subject to further adjustments to account for factors that may cause a hospital to incur greater-than-average costs, such as the treatment of a high number of low-income patients. 42 U.S.C. § 1395ww(d)(5).

The agency undertakes yearly notice-and-comment rulemaking on changes to the Part A prospective payment rates and related adjustments. 42 U.S.C. § 1395ww(d)(6) (requiring agency to publish an annual update of the methodology and payment rates by August 1); 42 C.F.R. § 412.8 (same). That annual rulemaking takes an average of 102 days to complete. Br. in Opp'n App. 1a-3a.

Medicare administrative contractors (formerly called "fiscal intermediaries") perform Part A payment functions on behalf of the agency. Pet. App. 3a. A hospital must file an annual "cost report" with the Medicare contractor. 42 C.F.R. §§ 413.20, 413.24. The contractor then issues a notice of the final amount of Medicare program reimbursement due the hospital for that period (called an "NPR"). 42 C.F.R. §§ 405.1803, 405.1807.

If amount-in-controversy and other requirements are satisfied, a hospital may appeal that final determination, or the contractor's failure to issue a timely final determination, to the Provider Reimbursement Review Board ("Board")—an administrative tribunal appointed by the Secretary. 42 U.S.C. § 1395oo(a)(1), (h); 42 C.F.R. §§ 405.1835-405.1877. When the Board determines that it lacks authority to decide a question of law or regulations relevant to an appeal, hospitals have the right to immediate judicial review of the underlying agency decision. 42 U.S.C. § 1395oo(f)(1).

In 1997, Congress created Medicare Part C, currently called "Medicare Advantage" and formerly known as "Medicare+Choice" or "M+C." Part C established a managed care program that is an alternative to the Part A fee-for-service program. 42 U.S.C. § 1395w-21(a). An eligible beneficiary can elect to receive benefits through enrollment in a managed care plan under Part C in lieu of benefits under Part A. *Id.* § 1395w-21(a)(1), (i)(1); *see Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6 (D.C. Cir. 2011).

II. THE AGENCY'S NEW STANDARD ON PART-A-ENTITLED DAYS IN THE DSH PAYMENT

A. The Part A DSH Payment Until 2004

As described above, the Medicare Part A rates paid to hospitals are subject to adjustments that account for factors causing a hospital to incur greater-than-average costs. One such adjustment is the "disproportionate share hospital" ("DSH") payment, which compensates hospitals for the additional costs

of providing services to low-income patients. 42 U.S.C. § 1395ww(d)(5)(F). The DSH payment turns on a "disproportionate patient percentage" that is the sum of two fractions representing inpatient care furnished to low-income individuals. *Id.* § 1395ww(d)(5)(F)(v), (vi). The two fractions depend, in inverse fashion, on the number of days spent in the hospital by patients who are "entitled to benefits under [Medicare] Part A." *Id.* § 1395ww(d)(5)(F)(vi)(I)-(II).

The first fraction, which the D.C. Circuit called the "Medicare fraction,"[1] measures the proportion of all hospital patients "entitled to benefits under [Medicare] Part A" (the denominator) who are also "entitled to supplementary security income [("SSI")] benefits" (the numerator). 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The agency determines and issues Medicare fractions for each federal fiscal year for all hospitals nationwide. Those fractions are binding on the agency when it issues final determinations of program reimbursement through its contractors, and on the hospitals for purposes of making claims for that reimbursement through cost reports. *See* 42 C.F.R. § 412.106(b)(2), (5); Pet. App. 12a.

The second fraction, the "Medicaid" fraction, measures the proportion of the total of all hospital patients (the denominator) who were Medicaid-

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[1] Respondents use this more general term for the Court's convenience, but under the statute, the fraction does not include all Medicare patient days, just those for patients entitled to Part A benefits. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I).

eligible but "not entitled to benefits under Part A" (the numerator). 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). The Medicaid fraction is determined by the Medicare contractor based on data furnished by the hospital in its cost report. 42 C.F.R. § 412.106(b)(4); 78 Fed. Reg. 50,496, 50,642 (Aug. 19, 2013).

Patients are either Part A entitled or not. Accordingly, a given patient can be counted in the numerator of one DSH fraction or the other, but not both. *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (*"Allina I"*).

To implement the DSH payment adjustment, including the determination of days in the DSH fractions, the agency has repeatedly used notice-and-comment rulemaking. *See* Br. in Opp'n App. 4a-6a. This includes at least six rulemakings to determine whether patient days not covered or paid under Medicare Part A are Part-A-entitled days, and ten other rulemakings to make changes to the treatment of other categories of days in the DSH payment. *See id.*

Before 2004, the agency considered Part C patients *not* entitled to benefits under Part A in calculating the DSH payment. *See* Pet. App. 4a ("Before 2004, HHS had *not* treated Part C enrollees as 'entitled to benefits under Part A.'") (citation omitted); *Allina I*, 746 F.3d at 1106, 1108 (agency "treated Part C patients as *not* entitled to benefits under Part A," "excluding Part C days from the Medicare fraction and including them in the Medicaid fraction") (citation omitted); *Northeast Hosp.*, 657 F.3d at 16-17 (2004 rule "contradicts [the agency's] former

practice of excluding [Part C] days from the Medicare fraction" as well as "longstanding" policy).

That approach reflected the original 1986 DSH regulation, which included as Medicare Part A entitled only patient days that were covered and paid under the Part A fee-for-service system. *See* 42 C.F.R. § 412.106(b)(2)(i) (2003) (defining Medicare fraction to include only "the number of *covered* patient days") (emphasis added); *see also id.* § 409.3 (defining "covered" as services for which payment is authorized); 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (explaining the Secretary's intent when regulation adopted to include only "covered Medicare Part A inpatient days"). Although the 1986 regulation did not expressly mention Part C patient days (as noted above, Part C came later), it necessarily excluded them as days not covered and paid under Part A. *See Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 921 n.5 (D.C. Cir. 2013) (noting that the pre-2004 regulation limited the Medicare fraction to "covered Medicare Part A inpatient days").

B. DSH Payment Changes Relating To Part C Patients

In 2003, the agency published a proposed rule "to clarify" that Part C days are excluded from Part-A-entitled days in the DSH fractions because they are not considered covered and paid under Part A. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003). As the agency explained, "once a beneficiary has elected to join [a Part C] plan, that beneficiary's benefits are no longer administered under Part A." *Id.*; *see Allina I*, 746 F.3d at 1106.

In a final rule published in August 2004, however, the agency engaged in a "volte-face." *Allina I*, 746 F.3d at 1109. It adopted the exact opposite standard: counting days not paid by Part A, including Part C days, as Part-A-entitled days in the DSH calculation. 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004); *see also Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 81 (D.D.C. 2012), *aff'd in part and rev'd in part*, 746 F.3d 1102 (D.C. Cir. 2014). Unlike the proposed rule, the final rule deleted the requirement that days must be "covered" by Medicare Part A to be included as Part-A-entitled days. *Compare* 42 C.F.R. § 412.106(b)(2)(i) (2003) *with* § 412.106(b)(2)(i) (2004); *see also* 69 Fed. Reg. at 49,246. The agency's only explanation for the about-face was that Part C patients "are still, in some sense, entitled to benefits under Medicare Part A." 69 Fed. Reg. at 49,099. In an impact analysis accompanying the 2004 final rule, the agency predicted that the Part C days change would not "have a significant impact on payments." 69 Fed. Reg. at 49,770.

In 2007, without providing notice or the opportunity for comment, the agency further amended the text of the DSH regulation governing Part C days to conform to the 2004 "policy change." 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007). The agency framed the action as a "technical correction." *Id.*; *see Northeast Hosp.*, 657 F.3d at 14 n.8 ("Because of a clerical error, the text of § 412.106 was not actually revised until 2007."). Following that amendment, the regulation provided that the Medicare fraction would include (and Medicaid fraction would exclude) not just "covered" Part A patient days, but all days for

"patients entitled to benefits under Medicare Part A [(or Medicare Advantage (Part C))]." 72 Fed. Reg. at 47,383-84 (amending 42 C.F.R. § 412.106(b)(2)(i)(B) and (iii)(B)).

C. Challenges To The 2004 Rule (*Northeast Hospital* And *Allina I*)

The agency initially attempted to apply the new 2004 rule to DSH payments for services rendered in prior years. The D.C. Circuit rejected that maneuver, finding the rule "change[d] the legal consequences of treating low-income patients" and thus could not be applied retroactively. *Northeast Hosp.*, 657 F.3d at 13-17.[2]

Although the agency contended that the 2004 rule "codified a longstanding policy," the D.C. Circuit found that its "treatment of M+C days prior to 2004 *** belie[d] [that] claim." *Id.* at 15. Rejecting the agency's reliance on a 1990 rule concerning patient days paid through other health maintenance organizations ("HMOs"), the court noted that the 1990 rule did not actually address the Part C program and was contradicted by the agency's practice and written guidance regarding Part C days. *Id.* at 15-16. The

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[2] The hospitals there also argued that the 2004 rule was inconsistent with the DSH statute's plain terms. A divided panel disagreed, holding that the statute "has not clearly foreclosed the Secretary's interpretation" but "has left a statutory gap *** for the Secretary *** to fill." *Northeast Hosp.*, 657 F.3d at 13. Concurring in the judgment, then-Judge Kavanaugh agreed with the hospitals that a patient who "receives Medicare benefits under Medicare Part C for a particular 'patient day'" is not "also 'entitled' for that same 'patient day' to Medicare benefits under Medicare Part A." *Id.* at 18.

D.C. Circuit also rejected the Secretary's contention that her decision not to count Part C days as Part A entitled prior to implementing the 2004 rule was a "result of data system errors." *Id.* at 16. The court found that argument "not convincing" given the agency's pre-2004 written guidance, its contemporaneous description of the 2004 rule as newly "'adopting a policy' of counting [Part C] M + C days in the Medicare fraction," and its 2007 description of the 2004 rule as announcing a "policy change." *Id.* at 15-16.

In 2009, while that initial case challenging the retroactive application of the 2004 rule was pending, the agency began to apply the 2004 rule to later years, beginning with Medicare fractions for 2007. It was not until then that hospitals across the country began to understand the financial implications of the rule change. *See Allina I*, 746 F.3d at 1107 ("When the Secretary, in 2009, published reimbursement calculations for FY 2007 ***, the petitioners learned that their payments would decrease by tens of millions of dollars per year.").

A group of hospitals, including Respondents, brought a challenge (the precursor to this case) alleging that the 2004 rule changing the Part C days policy was not the "logical outgrowth" of the 2003

proposed rule "clarifying" the agency's former policy.[3] *Allina I*, 904 F. Supp. 2d at 89. The hospitals also argued that the rule was arbitrary and capricious because the agency's "cursory explanation in the 2004 Final Rule" failed to acknowledge its departure from past policy and practice, and ignored the "financial impact" of that departure. *Id.* at 92-94. The district court agreed with the hospitals and vacated the 2004 rule on both grounds. *Id.* at 89-93, 95.

The D.C. Circuit affirmed the vacatur, finding that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. In so holding, it explained that "a party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, *i.e.*, one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction." *Id.* at 1108. The D.C. Circuit did not reach the reasonableness of the Secretary's decision-making in adopting the 2004 rule. *Id.* at 1111. The D.C. Circuit also did not reach the question of what procedures the agency would be required to follow in order to readopt the standard from the vacated rule. *Id.*

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[3] Like here, the Government there attempted to relitigate whether there had been any policy change. *See Allina I*, 904 F. Supp. 2d at 77 n.2 ("The Secretary's pretense in briefing the instant matter—that her current interpretation is entirely consistent with the past—is * ** clearly forestalled by *Northeast Hospital*. It is also irregular legal gamesmanship.").

D. The 2013 Prospective Rule

In mid-2013, while the Secretary's appeal in *Allina I* was pending before the D.C. Circuit, the agency engaged in a new prospective rulemaking on Part C days in the DSH payment as part of the annual inpatient prospective payment system rulemaking for 2014. 78 Fed. Reg. at 50,615. Effective October 1, 2013, the standard governing Part C days in the DSH calculation reverted to that articulated in the vacated 2004 rule. *See id.* at 50,619 (rule "readopt[ion]" applies to "FY 2014 and subsequent years" only).

E. This Case (*Allina II*)

1. In June 2014, sixteen days after the D.C. Circuit's mandate in *Allina I* vacating the 2004 rule, the Secretary issued 2012 Medicare fractions that included Part C days (consistent with the vacated 2004 rule) for hospitals nationwide. Pet. App. 5a-6a. Those fractions were published on the agency's website with an accompanying explanation that the fractions reflected the agency's decision to "includ[e] [Part C] Claims Submissions."[4] The agency proceeded without notice, comment opportunity, or explanation for the departure from the prevailing pre-2004 standard reinstated by the 2004 rule's vacatur.

Respondents filed appeals to the agency's Provider Reimbursement Review Board and requested expedited judicial review of their challenge to the renewed Part C days change. C.A. App. 89-167,

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[4] CMS, *DSH Adjustment and 2011-2012 File*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

178-248. The Board granted that request under 42 U.S.C. § 1395oo(f), concluding that it lacked authority "to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* [*I*] are legal." Pet. App. 56a-58a, 71a-73a.

Respondents then brought this suit. The district court granted summary judgment to the agency. It found that the issuance treating Part C patients as Part A entitled was an "interpretative rule" exempt from the APA's notice-and-comment requirement, and that Medicare Act Section 1395hh(a)(2) incorporated the APA's exemption. Pet. App. 34a, 36a, 44a. The district court did not address Respondents' arguments about the independent notice-and-comment requirement of Section 1395hh(a)(4) triggered by the 2004 rule's "logical outgrowth" failure. Pet. App. 19a-44a.

2. The D.C. Circuit unanimously reversed. It explained that the text of Section 1395hh(a)(2) "describes in fairly straightforward language when notice and comment is necessary"—namely, "for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'" Pet. App. 12a (citation omitted). The D.C. Circuit found all four elements "readily met." *Id.*

First, the D.C. Circuit reasoned that the agency's inclusion of Part C days as Part-A-entitled days in the 2012 Medicare fractions "is, at the very least, a 'requirement'" because those fractions, which must be

used for DSH payment determinations, "treat Part C enrollees as 'entitled to benefits under Part A.'" Pet. App. 12a-13a (citing 42 C.F.R. § 412.106(b)(2), (5)). Second, the 2012 issuance constituted a "change" because the agency's "baseline" before the invalidated 2004 rule "was to *exclude* Part C days from Medicare fractions." Pet. App. 13a (citing *Northeast Hosp.*, 657 F.3d at 15). Third, the D.C. Circuit found that the issuance promulgated a "substantive legal standard" because the fractions "define the scope of hospitals' legal rights to payment for treating low-income patients." Pet. App. 13a-14a. And fourth, because "[t]he fractions are used to calculate the payment that providers will receive for providing healthcare services to low-income patients," the inclusion of Part C days "governs 'payment for services.'" Pet. App. 14a. Consequently, "[t]he inclusion of Part C days means that the providers will now receive lower payments." *Id.*

The D.C. Circuit did not decide whether the "decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule" because it rejected the Government's argument that the Medicare Act incorporates the APA's exception for interpretive rules. Pet. App. 15a, 17a. The D.C. Circuit "respectfully disagree[d]" with decisions from other circuits on that specific point based on the plain text of Section 1395hh(a)(2). *Id.* "Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking." Pet. App. 15a. "On the contrary," the D.C. Circuit explained, "the text expressly *requires* notice-and-comment rulemaking. *** We must respect Congress's

use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 15a-16a.

The D.C. Circuit ruled, in the alternative, that "even if HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules, HHS would still not prevail" based on Section 1395hh(a)(4), another provision of the Medicare statute that "expressly required notice and comment in this case." Pet. App. 17a. The D.C. Circuit held that Section 1395hh(a)(4) precludes a provision from "becom[ing] legally operative until it has gone through notice-and-comment rulemaking" if that provision "is not a logical outgrowth of a previously published notice of proposed rulemaking.'" Pet. App. 17a-18a (citation omitted). The D.C. Circuit explained that "HHS could not circumvent this [Section 1395hh(a)(4)] requirement by claiming that it was acting by way of adjudication rather than rulemaking" because "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." Pet. App. 18a.

The Secretary's rehearing petition was denied, with no member of the court calling for a vote. Pet. App. 77a-78a, 79a-80a.

SUMMARY OF ARGUMENT

The D.C. Circuit held that two provisions of the Medicare Act, Section 1395hh(a)(2) and Section 1395hh(a)(4), independently require HHS to engage in notice-and-comment rulemaking before departing from the pre-2004 baseline for determining DSH

payments. That conclusion is correct and should be affirmed.

I. A. Section 1395hh(a)(2) requires notice and comment for (1) any "rule, requirement, or other statement of policy" (2) that "establishes or changes" (3) a "substantive legal standard" (4) governing "payment for services." 42 U.S.C. § 1395hh(a)(2). The Secretary's 2014 issuance falls squarely within that category of Medicare actions.

To start, the 2014 issuance "governs payments for services" because it directly affects DSH payments to hospitals for treating low-income patients—a point the Government here (despite its fluctuating views on the degree of payment impact) does not dispute.

The 2014 issuance is also the kind of agency action that can trigger the Medicare Act's notice-and-comment mandate. As the D.C. Circuit found, the 2014 issuance is at least a "requirement" (a term not used in the APA) as to DSH payments: The agency's Medicare fractions (and the standard they embody) are undisputedly binding on the agency's contractors in determining payments to hospitals, and even the agency's review Board concluded that it lacked authority to review their validity. In addition, the Government's own description shows that the 2014 issuance qualifies as a "statement of policy" guiding payment determinations. Its general application and future effect on payment rates also place it in the "rule" category. Neither the Government's ever-changing labels for its action nor its reliance on inapt precedent alters the commonsense conclusion that the

2014 issuance is the kind of agency instrument described in Section 1395hh(a)(2).

Next, the 2014 issuance made a "change." The vacatur of the 2004 rule restored the preexisting standard excluding Part C days from Part-A-entitled days in the Medicare fraction. From that baseline, the 2014 issuance plainly effected a change. The Government's retread position to the contrary—rejected in a 2011 D.C. Circuit decision on a full record and in subsequent decisions over years of litigation—cannot be squared with the relevant regulatory history.

Lastly, the 2014 issuance concerns a "substantive legal standard" because, as the D.C. Circuit found, the decision to include Part C days in the Medicare fraction "creates, defines, and regulates" the rights of hospitals. The statutory term "substantive legal standard" is not used in the APA and, regardless, should be understood according to its natural meaning as distinct from a "procedural" standard. The standard set by the 2014 issuance, filling a statutory gap to determine the treatment of Part C days, is anything but procedural.

B. The Government's principal argument—that Section 1395hh(a)(2) adopts the APA's "principles," and thus its "central distinction" between a "legislative" rule on the one hand and an "interpretive" rule lacking the "force and effect of law" on the other—is incompatible with the text, structure, and purpose of the Medicare Act. Far from incorporating the APA or its exemptions to notice and comment wholesale, Section 1395hh(a)(2) imposes a

different framework for notice-and-comment requirements specific to Medicare.

Under the Government's reading, only an agency issuance that already has "force of law" must go through the process typically used to give it that effect. But Section 1395hh(a)(2) explicitly *requires* notice and comment for a qualifying "statement of policy"—a type of issuance that ordinarily lacks the "force of law," and is categorically excluded from notice and comment under the APA. And making abundantly clear that Congress knew how to incorporate the APA's exceptions into the Medicare Act when it so intended, Section 1395hh(b)(2)(C) explicitly excuses the agency from notice-and-comment rulemaking under the Medicare Act when the APA's good-cause exception is satisfied. Congress's decision not to do the same for the APA's neighboring interpretive-rule exception speaks volumes.

The evolution of Section 1395hh's notice-and-comment requirement confirms what is readily apparent from the provision's text and structure. When it enacted Section 1395hh(a)(2), Congress took the unusual step of defining which policies HHS is required to promulgate through notice-and-comment regulation. Legislative history indicates that Congress was motivated to take that step based on a concern that "important policies [were] being developed without benefit of the public notice and comment period." H.R. REP. NO. 100-391(I), at 430. The Government's contrary characterization rests on out-of-context statements and speculative conclusions that ignore Congress's clearly articulated purpose.

II. Separate and apart from Section 1395hh(a)(2), Section 1395hh(a)(4) requires notice and comment in this case. That provision applies where, as here, a previous final rule has been invalidated for a "logical outgrowth" failure. In light of the 2004 rule's vacatur, the plain text of Section 1395hh(a)(4) precludes the inclusion of Part C days as Part A entitled from "taking effect" without notice and comment.

The Government's position—that HHS may avoid Congress's deliberate choice to require notice and comment following a logical-outgrowth failure by acting through instruments like the 2014 issuance that have the same nationwide effect—renders Section 1395hh(a)(4) a dead letter. Labeling it an "adjudication" cannot salvage the agency's end-run around Section 1395hh(a)(4) either, particularly in light of Section 1395hh(e)'s limitation on retroactive application of new policies—no matter how announced—to hospital services previously furnished.

III. Affirming the D.C. Circuit's decision will help, not hurt, the Medicare program. Congress required notice and comment for changes in substantive payment standards because hospitals must be able to plan and budget for health care services. They need an advance understanding of how much reimbursement they will receive from Medicare in order to fulfill their missions of serving the elderly and disabled beneficiaries in their communities. Accordingly, enforcing the Medicare Act's notice-and-comment requirements will facilitate planning of efficient and high-quality care for Medicare beneficiaries, which of course is the ultimate goal of the program.

The D.C. Circuit's holding will not impose the significant administrative burdens the Government suggests. In fact, its Section 1395hh(a)(4) holding has virtually no implications outside this case in light of the unique circumstances required to trigger that provision's notice-and-comment requirement. With respect to Section 1395hh(a)(2), the D.C. Circuit applied the plain terms of the statute to the unusual facts of this case—involving a change with billions of dollars at stake. Nothing about that holding will impose an undue burden on the agency, which already undertakes regular notice-and-comment rulemaking on a plethora of Medicare payment-related issues, including the DSH payment. Recent events, including a D.C. Circuit decision applying the decision below to find *no* notice-and-comment obligation under Section 1395hh(a)(2) for certain Medicare manual instructions, confirm that reality.

ARGUMENT

I. SECTION 1395hh(a)(2) REQUIRES NOTICE AND COMMENT HERE

When it enacted Section 1395hh(a)(2), Congress was concerned about the Secretary making sudden changes in Medicare payment standards without advance notice and input from the program's beneficiaries and service providers. For that reason, Congress created a notice-and-comment mandate unique to the Medicare program, instructing the agency to engage in notice-and-comment rulemaking whenever it issues a "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing *** payment

for services." 42 U.S.C. § 1395hh(a)(2). Unlike under the APA, the Medicare Act's notice-and-comment requirement applies if an agency issuance has the requisite standard-changing effect, regardless of the precise form of the issuance or the label the Government tries to affix. And it self-evidently applies to agency issuances—such as "statements of policy"—that are not "binding" on the agency or the courts and do not carry "the force and effect of law."

Because the 2014 issuance indisputably altered the legal consequences of treating low-income patients for hospitals across the country, it falls in the category of Medicare issuances subject to notice and comment. The Government's contrary arguments cannot be reconciled with the text, structure, or purpose of the Medicare Act.

A. The 2014 Issuance Fits Comfortably Within The Terms Of Section 1395hh(a)(2)

Section 1395hh(a)(2) requires notice and comment for the agency's renewed attempt at an about-face on Part C days in the DSH calculation. While the Government claims (contrary to its Petition) that the inclusion of Part C days as Part-A-entitled days would only "possibly reduce the amount of respondents' additional [DSH] payment" (Gov't Br. 4) (citation omitted), the Government (rightly) never disputes that the 2014 issuance "govern[s] *** payment for services." 42 U.S.C. § 1395hh(a)(2). And the issuance easily satisfies Section 1395hh(a)(2)'s other elements for triggering the notice-and-comment mandate.

1. "Rule, requirement, or other statement of policy"

a. As the D.C. Circuit found, the 2014 issuance "is, at the very least, a 'requirement.'" Pet. App. 12a. The Government admits that contractors (standing in for the agency's "own personnel") are *commanded* to use the Medicare fractions, which include Part C days as Part-A-entitled days, in calculating the amount of payment due to hospitals. Gov't Br. 5, 20. The contractors, acting on behalf of the agency, have no discretion on that issue. *See id.*

The Government asserts that the fractions are "based on" (Br. 11, 20, 37) and "reflect" (Br. 15, 17) a "nonbinding" interpretation of the DSH statute, and suggests a distinction between requirements on contractors and hospitals (Br. 40). But the Government does not and cannot dispute that hospitals are also *obligated* to use the published fractions (reflecting the agency's legal gap-filling) in their claims for DSH payments. 42 C.F.R. § 412.106(b)(2), (5).[5]

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[5] The Government also makes the puzzling claim that the term "requirement" does not mean what it says "in context." Gov't Br. 40. Rather than the Medicare Act, the Government invokes *American Hospital Association v. Bowen*, 834 F.2d 1037, 1051 (D.C. Cir. 1987). That APA case involved procedural enforcement-related "directives" to contractors engaging in "peer review" of Medicare outlays, which the court described as causing only "incidental inconveniences" for hospitals. *Id.* at 1041, 1051. It nowhere suggested that a requirement affecting both contractors *and* hospitals that *directly* results in substantially lower payments would be exempt from notice and comment

b. Tellingly, the Government makes no effort to explain why the 2014 issuance is not a "statement of policy." *See* Gov't Br. 39-41. The Government's contention that "not even respondents claim that their FY2012 fractions are 'statement[s] of policy'" (Br. 40) (alteration in original) is incorrect: Respondents made that argument below, and the Government (like here) offered no response. *See* Resp't C.A. Br. 25 ("[A]t the very least [the 2014 issuance] constituted a 'statement of policy.'"); Resp't C.A. Reply 11 ("The government does not dispute that *** the 2014 issuance is a *** 'statement of policy.'").

In fact, the Government's own description of the 2014 issuance demonstrates that it is (at a minimum) a "statement of policy." A statement of policy is typically "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (quoting Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947)); *see, e.g., Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) ("By issuing a policy statement, an agency simply lets the public know its current enforcement or adjudicatory approach.").

As the Government observes, when issuing "2012 Medicare fractions for hospitals nationwide," the agency explained that "the '[c]alculations *** includ[ed] [Part C] Claims Submissions.'" Gov't Br. 10

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under the APA (let alone under the yet-to-be passed Medicare Act provision imposing a separate notice-and-comment obligation for "requirement[s]").

(quoting *DSH Adjustment and 2011-2012 File*, p. 16, *supra*) (alterations in original). That explanation "reflected CMS's 'decision *** to include Part C days' in calculating the FY2012 Medicare fractions" based on its gap-filling "independent 'interpretation of the statute.'" Gov't Br. 11 (quoting Pet. App. 33a) (ellipses in original); *see Northeast Hosp.*, 657 F.3d at 13 (finding "statutory gap" in the DSH statute "for the Secretary *** to fill"). The Government further offers that the fractions "supply one aspect of the contractors' initial reimbursement determinations" and "are therefore just the first step in CMS's own administrative adjudicatory process." Gov't Br. 38. In that version of the Government's telling, then, the agency published a "statement of policy" to guide its adjudicatory approach to DSH payment determinations.

Notably, statements of policy are understood under the APA to be nonbinding. They "do[] not establish *** binding norm[s]" and are "not finally determinative of the issues or rights to which [they are] addressed." *American Hosp. Ass'n*, 834 F.2d at 1046 (citations omitted); *see also Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987) (citing multiple cases for proposition that statements of policy are not binding). For that reason, under the plain terms of Section 1395hh(a)(2), the Government's refrain that the challenged action could not trigger the Medicare Act's notice-and-comment requirement because it is "nonbinding" (*e.g.*, Gov't Br. 37-38) is misguided.

It is also wrong. As explained above, the issuance is binding on the agency's contractors and the

hospitals. The Government notes that contractor payment determinations are subject to review within the agency. Gov't Br. 38. But as the agency's Provider Reimbursement Review Board and the D.C. Circuit both held—and the Government no longer challenges—the Board had no authority to determine whether the 2014 issuance was valid and subject to the Medicare Act's notice-and-comment requirements. Pet. App. 10a-11a; *see id.* at 57a (Board explaining that it lacked authority "to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* [*I*] are legal"). Given this limitation on the Board's authority, the 2014 issuance was binding on the agency's adjudicators as well.

c. The 2014 issuance also qualifies as a "rule." Section 1395hh(a)(2) does not define that term or distinguish between different categories of rules. The Government itself describes "[t]he challenged agency action [as], at most, an interpretive rule" (Br. 17), and contends that it "most resemble[s] *** the challenged provision" in *Shalala v. Guernsey Memorial Hospital* (Br. 39), which this Court held was an APA "interpretive rule," 514 U.S. 87, 99 (1995).[6] The district court accepted the Government's argument

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[6] *Guernsey* does not otherwise support the Government's construction of Section 1395hh(a)(2). That case involved a manual instruction that predated Section 1395hh(a)(2), and was decided under the APA. *See* 514 U.S. at 87.

below that the 2014 issuance was such an interpretive rule. Pet. App. 33a-34a.

That characterization comports with the APA definition of "rule." *See* 5 U.S.C. § 551(4).[7] When the agency resurrected its decision to treat Part C days as Part A entitled for purposes of the DSH payment adjustment to the base Medicare rates, it did so for all DSH hospitals across the country. Pet. App. 14a; *see* Gov't Br. 10 (confirming nationwide effect). The 2014 issuance was therefore one of "general applicability." Pet. App. 14a. And it had "future effect" because it was used to determine interim DSH payments to hospitals until the next year's fractions were issued in May 2015. *Id.* at 15a; *see* 75 Fed. Reg. 50,042, 50,282 (Aug. 16, 2010) (noting agency practice of "using each hospital's latest available [Medicare] fraction in determining [Medicare] interim payments from the time that the *** fractions are published until the *** fractions for the next fiscal year are published"); *see also, e.g., Mobil Oil Corp. v. Federal Power Comm'n*, 469 F.2d 130, 139 (D.C. Cir. 1972) ("These actions constitute rulemaking, despite their temporary nature.") (citations omitted).

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[7] The APA defines "rule," in pertinent part, as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy *** and includes the approval or prescription for the future of rates." 5. U.S.C. § 551(4).

2. "Change"

a. Prior to 2004, the agency's standard for determining patient days "entitled to benefits under Part A" in the DSH calculation excluded Part C days. At the time Part C was enacted, the then-existing DSH regulation counted as Medicare Part A entitled only patient days that were covered and paid under the Part A fee-for-service system. *See* pp. 10-11, *supra* (discussing pre-2004 regulatory scheme). Accordingly, as the D.C. Circuit has observed in decisions dating back to 2011, "between 1999 and 2004, the Secretary routinely *excluded* [Part C] days from the Medicare fraction." *Northeast Hosp.*, 657 F.3d at 15; *see also id.* at 17 (rejecting agency's argument that the exclusion of Part C days was inadvertent and finding that it reflected a conscious policy choice); *see* pp. 10, 13-15, *supra* (citing similar decisions).[8]

The vacatur of the 2004 rule, which had attempted a "volte-face," *Allina I*, 746 F.3d at 1109, restored the pre-2004 standard. *See, e.g., Croplife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003) ("As a consequence [of vacating rule], the agency's previous practice *** is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated

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[8] When the agency announced in 2004 that it would begin to "include the patient days for [Part C] beneficiaries in the Medicare fraction" (along with other days not covered and paid under Part A), the agency removed the word "covered" from the regulation governing the Medicare fraction. *See* p. 12, *supra* (describing change in regulatory text); *see also* 69 Fed. Reg. 48,916 (Aug. 11, 2004).

regulation."). Although the agency promulgated a new rule after notice and comment in 2013 that included Part C days as Part-A-entitled days, all agree that rule has only prospective effect and does not apply to the DSH fractions issued for years before 2014. As a result, "the pre-2004 standard of excluding Part C days from Medicare fractions remains the baseline" from which to evaluate the standard reflected in the 2012 DSH fractions at issue here. Pet. App. 13a. The agency's decision to *include* Part C days in those 2012 Medicare fractions was plainly a change from that baseline.

b. The Government does not directly challenge the D.C. Circuit's conclusion that the 2014 issuance constituted a "change" from the existing standard.[9] The Government instead contends that the D.C. Circuit's holding "cannot be right" because the agency would not have been permitted to apply *any* standard, including the pre-2004 standard. Gov't Br. 43. That is because the initial "establishment" of a standard either including or excluding Part C days, the Government says, would have triggered Section 1395hh(a)(2)'s notice-and-comment requirement. *Id.*

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[9] At the tail end of its separate Section 1395hh(a)(4) argument, the Government attempts to relitigate the D.C. Circuit's decision in *Northeast Hospital* by claiming that the 1990 rule governing HMO days—not the 1986 DSH regulation—"established" the pre-2004 standard governing Part C days. Gov't Br. 49. The D.C. Circuit soundly rejected that assertion based on a well-developed administrative record (*see* pp. 13-14, *supra*), and the Government offers this Court no new basis to disagree with that established finding (*see* pp. 54-55, *infra*).

As explained, however, the agency had no reason to engage in further notice-and-comment rulemaking before excluding Part C days from the Medicare fraction. It had already established the relevant standard, embodied in the 1986 regulation, through notice-and-comment rulemaking. *See* p. 11, *supra*. Indeed, the agency applied that standard until it finally implemented the 2004 rule in 2009 by way of Medicare fractions for 2007.

In any event, the agency had ample opportunity to engage in notice-and-comment rulemaking after the enactment of Part C to properly establish that standard. *See* 42 U.S.C. § 1395w-26(b)(1) (affording the agency nearly ten months to promulgate regulations for Part C plans); *see also* p. 7, *supra* (describing annual notice-and-comment rulemaking for inpatient hospital prospective payment system that includes the DSH payment).

The Government's (self-described) failure to do so then does not excuse its failure to do so now. In other words, the fact that the accepted pre-2004 policy and practice of excluding Part C days from Part-A-entitled days might *also* have required notice and comment in no way undermines the D.C. Circuit's conclusion that the challenged 2014 issuance changing that standard was procedurally invalid.

3. "Substantive legal standard"

The agency's 2014 issuance concerns a "substantive legal standard," a term unique to Section 1395hh(a)(2). As the D.C. Circuit explained, "'[s]ubstantive law' is law that 'creates, defines, and regulates the rights, duties, and powers of parties.'"

Pet. App. 13a-14a (quoting BLACK'S LAW DICTIONARY (10th ed. 2014)). It follows that a "substantive legal standard" includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." *Id.* The 2014 issuance sets this kind of substantive legal standard. Like the vacated 2004 rule attempting to adopt the same standard, the 2014 issuance "attaches new legal consequences to hospitals' treatment of low-income patients." *Northeast Hosp.*, 657 F.3d at 17.

The "principles" and definition the Government prefers over the Medicare Act's text relate to an APA "substantive rule," not a "substantive legal standard" as that term is used in Section 1395hh(a)(2) of the Medicare Act. Gov't Br. 25, 27.[10] But Congress in the Medicare Act did not just incorporate the APA in one fell swoop or reiterate the requirements of the APA. Instead, Congress used distinct terminology to mandate notice-and-comment rulemaking for any "rule, requirement or other statement of policy" setting a "substantive legal standard." That language is naturally read to exclude agency issuances governing *procedure*, while covering those altering *substantive* rights. *See Welch v. United States*, 136 S. Ct. 1257, 1264-1265 (2016) (contrasting "substantive" legal standards, which "alter the range of conduct or the class of persons that the law punishes," with "procedural" ones, which "regulate only the manner of determining the defendant's culpability") (citations

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[10] Even the APA recognizes that a "substantive rule" can encompass a rule that is "interpretive" in nature. *See* 5 U.S.C. § 553(d)(1), (2) (exempting "interpretive rules" from requirement applicable to "substantive rule").

and emphasis omitted). Even the Government seems to recognize that its contrary interpretation strays from common meaning. *See* Gov't Br. 27 ("[u]nderstanding th[e] specialized distinction" on which the Government's claim rests "requires specialized sources").

American Hospital Association—the D.C. Circuit case the Government touts as having "inspired" Section 1395hh(a)(2) (Br. 40)—supports the distinction between substance and procedure. Throughout its decision in that case, the D.C. Circuit emphasized the distinction not just between legislative and interpretive rules, but also between those two categories of rules (taken together) and a third category: "rules of agency *** procedure" (5 U.S.C. § 553(b)(A)) or "procedural rules." *See* 834 F.2d at 1044-1045, 1050-1052. If, as the Government contends, Section 1395hh(a)(2) reflects *American Hospital Association*, the D.C. Circuit's understanding of "substantive legal standard" must be correct. As that court has elsewhere recognized, the provision excludes issuances that alter agency procedures, including those that "set forth an enforcement policy." *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 355-356 (D.C. Cir. 2017); *see also Am. Hosp. Ass'n*, 834 F.2d at 1056-57 & n.4 (describing issuances setting forth agency enforcement priorities as "procedural rules"). But it covers those that "create[], define[], and regulate[] the rights, duties, and powers of parties"—whatever their form. Pet. App. 13a-14a.

The Government also contends that "the statute," not the 2014 issuance, "sets the governing standard" for purposes of Section 1395hh(a)(2). Gov't Br. 20.

But the Medicare statute's parameters governing the DSH payment adjustment leaves a "statutory gap" for the agency to fill (*i.e.*, which patients are "entitled to benefits under Part A"). *Northeast Hosp.*, 657 F.3d at 13. Because the 2014 issuance fills that gap, the issuance reflects a "legal" choice. *Id.*; *see also* Gov't Br. 11 (describing 2014 issuance as "based on the agency's independent interpretation of the statute") (citation omitted).

That choice is the relevant "standard" here. Consistent with that view, the Government has repeatedly used notice-and-comment rulemaking to implement new or revised standards on different categories of patient days in the DSH payment, including Part C days. *See* p. 10, *supra*. The Government's theory would exclude a large category of issuances with far-reaching impacts on Medicare providers from notice-and-comment rulemaking—exactly what Congress endeavored to avoid when it enacted Section 1395hh(a)(2).

B. The Government's Cramped Conception Of "Substantive Legal Standard" Contradicts The Medicare Act's Text And Purpose

Recognizing the constraints of the Medicare Act's text, the Government finds comfort in the "principles" of the APA. But Congress did not import the APA framework into the Medicare Act. Rather, it set out to require notice and comment for agency instruments that the agency might otherwise have tried to make effective without undertaking that process. Although the agency might prefer the APA, a Congress well

aware of the APA's contours did not enact the Medicare Act's special rulemaking provisions to be redundant.

1. Section 1395hh(a)(2) requires notice and comment for agency issuances that otherwise lack the "force of law"

a. The Government argues that Section 1395hh(a)(2) excludes from its notice-and-comment requirement any agency issuance that lacks "'the force and effect of law'" because such an issuance necessarily cannot "change" a "substantive legal standard." Gov't Br. 22. The Government's circular argument proves too much: The Medicare Act, by its terms, contemplates notice and comment for particular kinds of agency issuances—"rule[s], requirement[s], or other statement[s] of policy"—that would not otherwise have "the force and effect of law." The Medicare Act requires the agency to give these issuances that legal force before they can "take effect."

The words "force and effect of law"—which the Government borrows from inapposite APA decisions—are nowhere found in the Medicare Act. The Government's "force of law" argument relies on *Perez v. Mortgage Bankers Association*, 135 S. Ct. 1199, 1204 (2015). But in that case, this Court explained that the reason interpretive rules lack the force of law is that they have not gone through notice-and-comment rulemaking. *Id.* at 1204 ("The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. But[,] [as the Government recognizes,] that convenience comes at a

price: Interpretive rules do not have the force and effect of law.") (citation omitted); *see also* Gov't Br. 23 (explaining that a "legislative-type rule" has "binding legal force *because* it has been promulgated pursuant to" notice and comment) (emphasis added) (citing *Chrysler Corp.*, 441 U.S. at 302-303). Accordingly, the Government's contention—that interpretive rules are necessarily excluded from Section 1395hh(a)(2)'s notice-and-comment requirement because they lack the force of law—merely begs the question.[11]

b. Even more critically, the Government's "force of law" argument altogether ignores that "statement[s] of policy" in particular are expressly included in Section 1395hh(a)(2) as a type of instrument that can "establish[] or change[] a substantive legal standard." 42 U.S.C. § 1395hh(a)(2).

As noted above, statements of policy are not "binding" either on the agency or on the courts under the APA rubric. *See* pp. 28-29, *supra*. Nor do statements of policy carry "the force of law."[12] *See Am.*

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[11] The D.C. Circuit did not decide "whether HHS's decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule," Pet. App. 15a, as opposed to a legislative-type rule. If this Court were to reverse the D.C. Circuit's interpretation of Sections 1395hh(a)(2) and (a)(4), it should remand for consideration of that unresolved question.

[12] The Government's attempt to equate "force of law" and "binding" (*see, e.g.*, Gov't Br 22) —neither of which appears in the Medicare Act—fails on both the facts (because the 2014 issuance is binding in every relevant respect, *see* pp. 26, *supra*) and the law. An APA interpretive rule is said to lack the "force of law" because it does not bind *courts*, even if it binds the agency

Hosp. Ass'n, 834 F.2d at 1046 (citations omitted). In fact, under the APA's framework, a statement of policy is markedly *less* capable of altering a legal norm than an interpretive rule. "Interpretive rules and policy statements are quite different agency instruments." *Syncor Int'l Corp.*, 127 F.3d at 94. With a policy statement, the "agency retains the discretion and the authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm." *Id.*

By expressly including statements of policy among the types of issuances capable of triggering the notice-and-comment mandate, Congress made clear that Section 1395hh(a)(2) is not limited to agency issuances that carry "the force and effect of law." The Government's interpretation of "substantive legal standard" effectively reads "statements of policy" out of the statute (as well as "requirement[s]" that may also lack the force of law).

The Government also renders unnecessary Section 1395hh(a)(2)'s exclusion of "national coverage determinations" from its notice-and-comment requirement. *See* 42 U.S.C. § 1395hh(a)(2) (specifying any "rule, requirement, or other statement of policy

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(including its contractors and adjudicators). *See Chrysler Corp*, 441 U.S. at 308 (equating "binding effect of law" with being "binding on courts in a manner akin to statutes"); *see also* Gov't Br. 24 ("*courts* are *** not required" to give interpretive rules "binding effect of law") (emphasis added). It is passing strange to suppose that Congress's purpose to increase opportunities for public input (*see* pp. 44-45, *infra*) would be satisfied by a system where that opportunity comes by way of an after-the-fact lawsuit.

(*other than a national coverage determination*)") (emphasis added). Prior to Section 1395hh(a)(2)'s enactment, national coverage determinations were not issued through notice-and-comment rulemaking. *See* Omnibus Budget Reconciliation Act of 1986, § 9341 (providing that national coverage determinations were not to be "held unlawful or set aside" for failure to engage in notice and comment). If the Government were correct that Section 1395hh(a)(2)'s reference to a "substantive legal standard" limits the notice-and-comment requirement to legislative-type rules, there would have been no need for Congress to carve out national coverage determinations. As instruments "lacking the force and effect of law," they would have been excluded already.

c. Similarly, the Government gives short shrift to Section 1395hh(b)(2)(C), which demonstrates that Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it intended to. Citing the section of the United States Code setting out the APA's rulemaking exceptions, the Medicare Act explicitly cross-references the good-cause exception. *See* 42 U.S.C. § 1395hh(b)(2)(C) (excusing notice and comment if "subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection"); *see also* 5 U.S.C. § 553(b)(B) ("good cause" exception).

In stark contrast, even though the APA's interpretive-rule exception is set out in the subparagraph immediately preceding the good-cause exception (Section 553(b)(A)), Congress did *not* cross-reference that exception—or any other APA exception

apart from good cause—in the Medicare Act. That deliberate omission leaves no doubt as to Congress's intent. *Cf. Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (alteration in original).

It is no answer to claim, as the Government does that "[t]here is *** no need for an express *exception* from that requirement for interpretive rules, because interpretive rules already are excluded from the scope of notice-and-comment rulemaking in the first place." Gov't Br. 28 (emphasis in original). Having explicitly cross-referenced one APA exception in Section 1395hh, it is inconceivable that Congress would hide another in a novel statutory phrase. Put simply, if Congress had intended to exclude interpretive rules from the scope of Section 1395hh(a)(2), it would have done so expressly.[13]

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[13] The Government's reference to the holdings of "other courts of appeals" that Section 1395hh(a)(2) "does not apply to interpretive rules" (Gov't Br. 28) is misleading. Those courts largely assumed, in footnotes without analysis (and not explicitly deciding), that the Medicare Act incorporated the APA's exceptions. *See, e.g., Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998); *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004). None adopted the new reasoning the Government offers this Court: that "substantive legal standard" should be read to exclude instruments that lack the force of law. Indeed, at the D.C. Circuit, the Government simply argued that the Medicare Act incorporated the APA's exception for interpretive rules *sub silentio*.

d. Several other surrounding provisions further undermine the Government's premise that an interpretive rule (or, a fortiori, a statement of policy) cannot change a "substantive legal standard" under Section 1395hh(a)(2). Section 1395hh(e)(1)(A) confers limited retroactive rulemaking authority for, inter alia, "substantive changes in *** interpretative rules, statements of policy, and guidelines of general applicability." That the Medicare Act contemplates "substantive changes" as part of an interpretive rule or statement of policy strongly supports the conclusion that those instruments can in fact change a "substantive legal standard" under the Medicare Act.

Section 1395hh(c)(1)(B) cuts the same way. That section imposes a separate obligation for the Secretary to "publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which *** are promulgated to carry out this subchapter, but *** are not published pursuant to subsection (a)(1)." In other words, it requires a published list of policy statements, rules, and instructions that do *not* trigger the notice-and-comment mandate of Section 1395hh(a)(2). That requirement presupposes that some such instruments must be issued via notice and comment.

The Government responds that Section 1395hh(c)(1)(B) does not shed light on Section 1395hh(a)(2) because the agency may engage in voluntary rulemaking. Gov't Br. 29. Anytime the agency issues interpretive rules through notice and comment, the Government contends, it does so voluntarily. *Id.* That unsupported contention not only

lacks any grounding in the statutory text, but it is contradicted by the legislative history of Section 1395hh(c)(1)(B). *See* H.R. REP. NO. 100-495, at 563 (1987) (Conf. Rep.) (Congress describing provision as necessitating publication of a list of "interpretative rules" "which *** are not published *as required* by [Section 1395hh(a)(2)]") (emphasis added).

2. Legislative history and context show Congressional intent to expand notice and comment

The evolution of the Medicare Act's notice-and-comment requirement reinforces the conclusion that Congress intended to expand the notice-and-comment obligations of the Secretary beyond what the APA requires.

Congress first added a notice-and-comment requirement to the Medicare Act in 1986, long after the agency had committed to following the APA. *See* 36 Fed. Reg. at 2,532 (stating in 1971 that the agency would "utilize the public participation procedures of the APA" in issuing "rules and regulations relating to *** benefits"). In that first enactment, Congress obligated the Secretary to provide 60 days for comment before publishing a Medicare regulation except in certain circumstances (such as when the APA's "good cause" exemption applies). *See* Omnibus Budget Reconciliation Act of 1986, § 9321(e). If there was a need to hold the agency to its notice-and-comment policy, *see* Gov't Br. 31, the 1986 enactment fully satisfied it.

But Congress did not stop there. Just one year later, in the face of widespread complaints about

standards governing payment still being issued without notice and comment, Congress revisited the specific Medicare rulemaking obligation. Noting its concern that "important policies [were] being developed without benefit of the public notice and comment period" because the Medicare Act did not "define a regulation for that [rulemaking] purpose," Congress took the unusual step of specifying "those policies which must be subject to the rulemaking procedures." H.R. REP. NO. 100-391(I), at 430.

In setting out the standard now codified in Section 1395hh(a)(2), Congress made clear that it intended to subject more policies to notice and comment than the agency had been promulgating through that process when it had been following the APA. In the initial House bill, the notice-and-comment requirement applied to any "rule, requirement, or other statement of policy" with a "significant effect on *** the payment for services." H.R. REP. NO. 100-495, at 563. The Conference Committee amended the provision's rulemaking trigger to the change or establishment of a "substantive legal standard" governing payment for services.

Congress never indicated that the change in wording was intended to have a limiting effect in the way the Government describes here. To the contrary, Congress stated its continued understanding that, pursuant to the conference amendment, any "[s]ignificant policy changes would be required to be promulgated as regulations." House Ways and Means Committee, Summary of Reconciliation Provisions, 12-13 (Dec. 22, 1987). Underscoring the breadth of the

notice-and-comment requirement, the heading enacted by the full Congress described the final provision as requiring "publication as regulations of significant policies," Omnibus Budget Reconciliation Act of 1987, § 4035 (capitalization omitted). The amendment therefore did not narrow the notice-and-comment requirement so as to exclude agency pronouncements like the 2014 issuance; if anything, it obviated any debate about the "significance" of such a pronouncement's "effect on payment."

The committee report's accompanying reference to "recent court rulings" (without citation) does not help the Government either. Even accepting the Government's speculation that the conferees were referring to the APA rulings that the Government chooses to cite, none of those discusses the phrase "substantive legal standard." And as discussed above, the case on which the Government primarily relies—the D.C. Circuit's decision in *American Hospital Association*—actually supports Respondents' reading that the phrase is intended to exclude only procedural (as opposed to substantive) pronouncements. *See* pp. 35-36, *supra*.

Finally, the Government claims that "nothing in the drafting history so much as hints that Congress had some other, novel administrative rulemaking procedures in mind when it enacted Section 1395hh(a)(2)." That is incorrect. The drafting history not only "hints" that Congress intended to create a separate notice-and-comment requirement under the Medicare Act, the history proves it. Congress did *not* import the APA's notice-and-comment requirement applicable only to certain rules, and it did *not* adopt

all of the APA's exceptions from that requirement when it dictated which agency issuances would be promulgated through notice and comment in 1987. To the contrary, it expressly included statements of policy (part of the APA's exception in 5 U.S.C. § 553(b)(A) and requirements (not mentioned in the APA) among the specific issuances subject to notice-and-comment rulemaking. Indeed, it is not clear what work the 1987 amendment does under the Government's theory. If the agency was statutorily obliged to follow the APA (with all its attendant exceptions) in 1986, and those same obligations and exceptions apply following the 1987 amendment, then the 1987 amendment accomplished nothing.

II. SECTION 1395hh(a)(4) INDEPENDENTLY REQUIRES NOTICE AND COMMENT HERE

Section 1395hh(a)(4) obligated HHS to undertake notice and comment before the change attempted by the vacated 2004 rule could again "take effect." That separate statutory provision, which applies *only* when a prior rule has been invalidated for a logical-outgrowth failure, is tailor-made for this case.

A. The Plain Terms Of Section 1395hh(a)(4) Require Notice And Comment In Light Of The 2004 Rule's Logical-Outgrowth Failure

Section 1395hh(a)(4) issues specific instructions to the agency: If a final regulation includes a provision that is not a "logical outgrowth" of the proposed regulation, then "*such* provision shall not take effect until there is the further opportunity for public

comment" and publication as a "final regulation." 42 U.S.C. § 1395hh(a)(4) (emphasis added).

When the agency—without providing a "further opportunity for public comment"—adopted in the 2014 issuance the same standard for Part-A-entitled days as in the vacated 2004 rule, it flouted Section 1395hh(a)(4)'s mandate. Section 1395hh(a)(4) does not permit a provision of a final rule invalidated for a "logical outgrowth" failure, such as the provision of the 2004 rule including Part C days as Part A entitled, to "take effect" through an instrument like the 2014 issuance. Without notice and comment, such a provision "shall not" become legally operative so as to alter the rights and obligations of regulated parties. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 397 (11th ed. 2012) (defining "effect" as "the quality or state of being operative"). But the 2014 issuance had precisely that (impermissible) result—mandating reduced DSH payments to hospitals for serving low-income patients.

As the Government recognizes (Br. 44), Section 1395hh(a)(4) is another departure from the APA. Under the APA, courts are directed to give "due account *** of the rule of prejudicial error," 5 U.S.C. § 706(2)(F), and have allowed procedurally invalid rules to stand without vacatur if the party challenging the rule cannot show that it was prejudiced by the error. *See, e.g., Allina I*, 746 F.3d at 1109-10 (discussing harmless-error rule and citing cases). Section 1395hh(a)(4) eliminates harmless-error analysis when a Medicare Act regulation has been invalidated for a logical-outgrowth failure: regardless

of prejudice, the offending provision will not "take effect."

B. The Applicability Of Section 1395hh(a)(4) Does Not Depend On How The Agency Tries To Make The Previously Invalidated Rule Take Effect

The Government contends that Section 1395hh(a)(4) has no application in this case because: (1) the 2014 issuance was not promulgated or required to be promulgated through a notice-and-comment regulation, and (2) the agency purportedly proceeded through adjudication without relying on the vacated 2004 rule. Neither allows the agency to dodge the requirements of Section 1395hh(a)(4).

1. The readoption of the 2004 rule need not take the form of a notice-and-comment regulation to trigger Section 1395hh(a)(4)

As the Government would have it, because Section 1395hh(a)(4) provides that an invalidated regulation cannot "take effect" without notice, comment, and republication as a "final regulation," only "final regulations"—*i.e.*, those that go through notice-and-comment rulemaking—trigger that provision. *See* Gov't Br. 44-45. That defies common sense.

For starters, the Government relies on the opening clause of Section 1395hh(a)(4) to argue that it applies only "[i]f the Secretary publishes a final regulation." Br. 18-19, 44 (alteration in original) (citation omitted). It then argues that because the

2014 issuance was not published as a final regulation, it falls outside the provision. *Id.* at 44-45. But Section 1395hh(a)(4)'s reference to "final regulation" in its opening clause clearly refers not to the agency action *after* the invalidation of a regulation, but to the original invalidated "final regulation that includes a provision that is not a logical outgrowth of" the proposed regulation, 42 U.S.C. 1395hh(a)(4)—here, the *2004 rule*.[14]

In reality, Section 1395hh(a)(4)'s later reference to "publication of the provision again as a final regulation" establishes the full contours of the Secretary's notice-and-comment obligation: a provision previously invalidated for a logical-outgrowth failure may become operative *only* as a final regulation issued through notice and comment. Accordingly, the question whether a particular issuance triggers Section 1395hh(a)(4) turns not on whether the agency has newly undertaken notice and comment as the Government claims, but on whether the agency tries to make the previously vacated provision of a prior invalidated rule "take effect."

The government's argument ignores the use of the same "take effect" language in Section 1395hh(a)(2), which bars any qualifying "rule, requirement, or other statement of policy" from

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[14]For the same reason, the Government's contention that "[i]t would make no sense to 'treat[]' [the 2014 issuance] *** 'as a proposed regulation'" (Br. 45 (quoting 42 U.S.C. § 1395hh(a)(4)) misses the mark. Section 1395hh(a)(4) does not require that the *2014 issuance* be treated as a proposed regulation; it requires such treatment for the vacated *2004 rule* in the context of new notice-and-comment rulemaking.

"tak[ing] effect" "unless it is promulgated by the Secretary *by regulation*." 42 U.S.C. § 1395hh(a)(2) (emphasis added). The explicit bar in Section 1395hh(a)(2) on qualifying issuances "tak[ing] effect" *absent* notice-and-comment rulemaking presumes that such issuance otherwise *could* very well otherwise "take effect" despite not being promulgated through notice-and-comment procedures. Because "take effect" means the same thing in Section 1395hh(a)(2) and (a)(4) (which even the Government agrees it must (Br. 44-45)), the "take effect" prohibition in Section 1395hh(a)(4) cannot apply only when an issuance readopting a provision of an invalidated final rule is later promulgated via notice-and-comment regulation.

As described above, the vacated 2004 rule "t[ook] effect" when the agency included Part C days as Part-A-entitled days in the Medicare fractions for all hospitals nationwide. When it actually published the renewed determination in 2014 to include Part C days as Part-A-entitled days, the agency offered no explanation for the standard's readoption, never mind any denial that it was applying the 2004 rule or the 2013 rule accomplishing the same. That the agency claims in a made-for-litigation affidavit that it did not "rel[y] on the vacated rule" itself in issuing the fractions (Gov't Br. 46) and instead applied the identical (invalidated) standard (as reflected in the agency's accompanying explanation) makes no difference.

As this case makes clear, the Government's interpretation of Section 1395hh(a)(4) creates an exception that would swallow it altogether. In the

Government's view, an agency issuance violates Section 1395hh(a)(4) *only if* the agency retains and implements a final regulation invalidated for logical-outgrowth failure. That result cannot be reconciled with Congress's deliberate decision in Section 1395hh(a)(4)—separate and apart from Section 1395hh(a)(2)—to require a new notice-and-comment period following a regulation's logical outgrowth-failure. And to the extent the Government makes the argument that Section 1395hh(a)(4) truly has no "independent force" (Br. 44-45) and rises and falls with Section 1395hh(a)(2), that argument defeats itself: Congress does not pass statutory provisions as window dressing. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31, (2001) ("[A] statute ought *** to be so construed that *** no clause, sentence, or word shall be superfluous, void, or insignificant.").

2. The agency's claim that it proceeded through adjudication does not avoid Section 1395hh(a)(4)

The agency's general authority to act through adjudication does not salvage the 2014 issuance. As an initial matter, the fractions do not "represent[] the agency's choice to proceed by adjudication rather than by rulemaking." Gov't Br. 46. The agency issued the fractions treating Part C days as Part A entitled for all DSH hospitals nationwide. That is not the "individual, *ad hoc* litigation" that typifies adjudication. *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947); *see* Pet. App. 18a (D.C. Circuit rejecting Government's claim it was proceeding through adjudication); Pet. App. 33a (district court rejecting same). Indeed, the Government otherwise calls the 2014 issuance "at

most" an interpretive rule, and describes it like a statement of policy. *See* pp. 27-30, *supra*. The fact that the fractions "supply one aspect" (Br. 38) of payment determinations does not convert the issuance into an adjudication. Under the government's theory, any substantive policy statement on Medicare payment rates could be an adjudication because all affect payment determinations.

But even if the 2014 issuance could qualify as an adjudication, it would still violate Section 1395hh(a)(4). Whether a provision previously invalidated for a logical-outgrowth failure "take[s] effect" through an "individual, *ad hoc* litigation," *Chenery Corp.*, 332 U.S. at 203, or (as here) through an issuance that applies simultaneously to hospitals across the country, the result is the same (here, the deprivation of significant payment for services to low-income patients). And it is precisely the result that Section 1395hh(a)(4) forbids.

Section 1395hh(e)(1), enacted at the same time as Section 1395hh(a)(4) (*see* pp. 6-7, *supra*), buttresses the conclusion that the form of the agency action does not matter under Section 1395hh(a)(4). Whether acting through rulemaking or adjudication, HHS may not apply "substantive changes" in regulations, interpretive rules, or statements of policy retroactively absent the requisite findings, and may not do so at all to enforce a new policy against a provider for services previously rendered. It is inconceivable that Congress intended to permit the agency in 2014 to act through "adjudication" and reinstate a policy covering 2012 services that was vacated for logical-outgrowth failure—*i.e.*, the *exact* circumstances governed by

Section 1395hh(a)(4)—when it could not make such a "substantive change" retroactively *even in the absence of a prior vacated rule* under Section 1395hh(e)(1).

The Government contends that the 2004 rule's vacatur left it "little choice but to address the handling of Part C patients by adjudication." Br. 48. Not so. Because the preexisting DSH regulation set forth a standard on Part-A-entitled days that excluded Part C days (pp. 11, 31, 33, *supra*), the agency could have (and should have) returned to the pre-2004 policy without any further action. The Government's (rehashed) claim that its pre-2004 standard in fact *included* Part C days in the Medicare fraction was rejected by the D.C. Circuit in an exhaustive 2011 opinion that examined agency policies dating back decades based on a full administrative record. *See Northeast Hosp. Ass'n*, 657 F.3d at 16; *see also* pp. 13-14, *supra*. The Government's attempt to relitigate that decision is too little, too late.

Regardless, the Government's claim that it had "little choice" but to act through adjudication falls flat no matter what standard came into effect following the 2004 rule's vacatur. Despite its statutory mandate to provide DSH payments, the agency has regularly delayed issuing DSH fractions—including in response to the *Allina I* litigation. *See* J.A. 24-26 (explaining that contractors were instructed to "immediately stop the issuance of Notices of Program Reimbursement (NPRs) for any cost reports that utilize a Social Security Income (SSI) ratio for determining DSH hospital payments, until further notice").

Moreover, the Medicare statute contemplates avoidance of notice-and-comment rulemaking when the agency can genuinely satisfy the good-cause exception, and permits retroactive rulemaking in certain limited circumstances. *See* 42 U.S.C. §§ 1395hh(b)(2)(C), (e)(1)(C). If the agency could not meet the statutory requirements for either good cause or retroactive rulemaking following the 2004 rule's vacatur, the answer was not to re-impose the same standard anyway. Whether framed as an adjudication or something else, that action violated Section 1395hh(a)(4).

III. AFFIRMING THE D.C. CIRCUIT'S DECISION WILL HELP, NOT HINDER, THE MEDICARE PROGRAM

The Government's brief (Br. 41-43) warns of the impact of the D.C. Circuit's decision on the agency's ability to administer the Medicare statute. But the singular focus on the agency's administrative burden ignores the many ways in which notice-and-comment rulemaking helps the Medicare system as a whole run more smoothly to the benefit of the elderly and disabled patients it serves. And the picture the Government paints about the supposed burden of rulemaking is divorced from the realities of the Medicare system and the tailored notice-and-comment requirements of Sections 1395hh(a)(2) and 1395hh(a)(4).

A. The Section 1395hh(a)(4) Holding Should Have Virtually No Implications Beyond This Case

As an initial matter, if the Court were simply to affirm the D.C. Circuit's Section 1395hh(a)(4) holding, the impact of its decision would be extremely limited. Section 1395hh(a)(4) applies in particular circumstances that are all but unique to this case. Leaving aside prior litigation over Part C days, no court has invalidated a Medicare rule for a logical-outgrowth failure, and only a handful of decisions have *ever* cited Section 1395hh(a)(4). *See* Br. in Opp'n 23-24 & n.4. Unless the Government intends to make a new habit of logical-outgrowth failures, Section 1395hh(a)(4) is unlikely to play any meaningful role in the administration of Medicare.

B. The Section 1395hh(a)(2) Holding Is Appropriately Narrow

The Government is also wrong to suggest that affirming the D.C. Circuit's Section 1395hh(a)(2) holding will have wide-ranging negative implications for the operation of Medicare.

First, to the extent that the holding changes the agency's Medicare practices at all, those changes will improve the program's ability to serve Medicare beneficiaries. Enacting more policies through notice and comment will increase predictability in the Medicare program and improve agency decision-making, including by prompting serious consideration of important factors such as financial impact. When providers are aware of the standards governing payment and can plan for reimbursements in advance,

they are better equipped to serve Medicare beneficiaries. Because the Medicare program makes $120 billion in expenditures each year just for inpatient hospital services and $675 billion in total, *see* https://www.cms.gov/fastfacts/, even seemingly small changes in payment standards yield significant changes in reimbursement for hospitals, *see County of Los Angeles v. Shalala*, 192 F.3d at 1010 ("Given the enormity of the Medicare program, *** seemingly modest percentage differences represent substantial sums of money.").

One need not look further than this case: As the Government admitted when it sought certiorari (after years of denials), whether Part C days are included in the Medicare fraction or the Medicaid fraction "makes a huge difference in the real world" (Pet. App. 4a) to hospitals. *See* Pet. 14 (asserting that the issue in this case affects $3 to $4 billion in Medicare payments). Indeed, avoiding the kind of "sticker shock" that occurred when the agency ultimately began treating Part C days as Part A entitled is precisely why Congress enacted Section 1395hh(a)(2). The Government now appears to backpedal on the financial impact it touted in order to obtain certiorari. *See* Gov't Br. 4-5. But the Government's apparent inability (or unwillingness) to acknowledge the financial impact of its change—even 14 years after first attempting to adopt it—only underscores the need for notice and comment.

In any event, affirming the D.C. Circuit is unlikely to change administrative practice to any great degree. Contrary to the Government's claim (Br. 42), the publication of binding fractions reflecting a

renewed change in national Medicare DSH payment policy has no bearing on the agency's ordinary use of instructions and manual guidance to its contractors. The publication of Medicare fractions is not a mere "instruction" to Medicare contractors. As described above (pp. 9, 26, *supra*), the fractions and the policy embodied in them are binding on all hospitals nationwide when they seek DSH payments in filing Medicare cost reports, and binding on the agency and its contractors in making payment determinations based on those cost reports. *See* 42 C.F.R. § 412.106(b)(2), (5) (requiring hospitals, the agency, and its contractors to use the agency's published Medicare fraction in calculating DSH payments).

By contrast, many contractor instructions neither (i) "establish[] or change[] a substantive legal standard," nor (ii) concern "the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits." 42 U.S.C. § 1395hh(a)(2). Section 1395hh(a)(2), by its terms, would not subject such mine-run procedural instructions to its notice-and-comment requirement.[15]

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[15] *See, e.g.*, Medicare General Information, Eligibility, and Entitlement Manual, CMS Pub. 100-01, ch. 6, §§ 10.1-10.4 (addressing release of information under Freedom of Information Act by CMS and its contractors), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c06.pdf; Medicare General Information, Eligibility, and Entitlement Manual, CMS Pub. 100-01, ch. 7, §§ 30-30.90 (describing record retention requirements for contractors), *available at* https://www.cms.gov/

Indeed, the D.C. Circuit has already had occasion to apply the decision below to certain Medicare manual instructions. It declined to require notice and comment, confirming the limited nature of its ruling in this case. *See Clarian Health West*, 878 F.3d at 356 (rejecting application of Section 1395hh(a)(2) to Medicare manual instructions governing enforcement as to reconciliation of special outlier payments). So it is utter hyperbole to suggest that the decision below "would, if taken to its logical conclusion, require CMS to promulgate all of its manuals and instructions, including the Provider Reimbursement Manual, through notice and comment." Gov't Br. 18.

Finally, contrary to the Government's suggestion, notice-and-comment rulemaking for Medicare payment standards, including for the DSH payment, is already the norm. Such rulemakings take a few months (not years, as the Government claims, Br. 42). As described above (p. 7, *supra*), the agency undertakes annual notice-and-comment rulemaking—taking an average of 102 days—for the inpatient hospital prospective payment system that includes the DSH payment. To the extent the D.C. Circuit's decision will result in fewer "guidance documents that effectively bind the public *without* undergoing the notice-and-comment rulemaking

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Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c07.pdf; Medicare Financial Management Manual, CMS Pub. 100-06, ch. 8, § 80.1 (describing contractor's qualifications for conducting a provider audit), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/fin106c08.pdf.

process," that would be consistent with current Executive Branch regulatory and enforcement policy. Memorandum from Associate Attorney General to Heads of Civil Litigating Components and United States Attorney, *re: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases* (Jan. 25, 2018) (emphasis added); *see also Caring Hearts Personal Home Services, Inc. v. Burwell*, 824 F.3d 968, 976-77 (10th Cir. 2016) (Gorsuch, J.) (noting that "Madison worried about *** a world in which the laws are 'so voluminous they cannot be read' and constitutional norms of due process, fair notice, and even the separation of powers seem very much at stake").

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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ADDENDUM

ADDENDUM

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5 U.S.C. § 551

Definitions

For the purpose of this subchapter—

* * * *

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

* * * *

5 U.S.C. § 553

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved--

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include--

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply--

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except--

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

42 U.S.C. § 1395w-21 (2012)

Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare+Choice plans

(1) In general

Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter--

(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w-101 of this title.

* * * *

(3) Medicare+Choice eligible individual

(A) In general

In this subchapter, subject to subparagraph (B), the term "Medicare+Choice eligible individual" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

* * * *

42 U.S.C. § 1395hh (1982)

Regulations

The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

42 U.S.C. § 1395hh (Supp. IV 1986)

Regulations

(a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(b)(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

42 U.S.C. § 1395hh (1988)

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where--

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which--

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

* * * *

42 U.S.C. § 1395hh.

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

* * * *

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed

rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where--

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules,

statements of policy, and guidelines of general applicability which--

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

* * * *

(e) Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

* * * *

42 U.S.C. § 1395oo.

Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (h) of

this section and (except as provided in subsection (g)(2) of this section) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if--

(1) such provider--

(A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1395ww of this title,

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(b) Appeals by groups

The provisions of subsection (a) of this section shall apply to any group of providers of services if each provider of services in such group would, upon the filing of an appeal (but without regard to the $10,000 limitation), be entitled to such a hearing, but only if the matters in controversy involve a common question of fact or interpretation of law or regulations and the amount in controversy is, in the aggregate, $50,000 or more.

* * * *

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's

decision, reverses, affirms, or modifies the Board's decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to

the matter in controversy contained in such request for a hearing. Such action shall be brought in the district court of the United States for the judicial district in which the provider is located (or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia and shall be tried pursuant to the applicable provisions under chapter 7 of Title 5 notwithstanding any other provisions in section 405 of this title. Any appeal to the Board or action for judicial review by providers which are under common ownership or control or which have obtained a hearing under subsection (b) of this section must be brought by such providers as a group with respect to any matter involving an issue common to such providers.

* * * *

42 U.S.C. § 1395ww.

Payments to hospitals for inpatient hospital services

* * * *

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographic Classification Review Board

* * * *

(5)(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which--

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

* * * *

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds--

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified

as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of--

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the

number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

* * * *

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

42 C.F.R. § 412.106 (2003)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation*: Federal fiscal year. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of covered patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may

include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

42 C.F.R. § 412.106 (2004)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation*: Federal fiscal year. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may

include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

42 C.F.R. § 412.106 (2007)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (or Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that

period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The

intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

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42 C.F.R. § 412.106

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

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(b) *Determination of a hospital's disproportionate patient percentage*—(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A

(including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(iv) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written notification must specify the methodology

the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

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